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ABSTRACT

A pharmaceutical composition for the treatment and/or prophylaxis of diseases caused by type I hypersensitivity reactions consisting essentially of Glicophosphopeptical, or pure Nigella Sativa seeds, in a concentration which stimulate Th1 lymphocytes and selectively switch-off the eosinophilic airway inflammation

A method of treatment of allergy using Th1 stimulating agents, to be administered to a mammal such as human in need of such treatment in a shot of 5 days only, resulted in significant decrease in symptom score started day 3, and in sputum eosinophils by day 14, followed by long-term clinical remission of a mean of 6 months.

The BCG-like Th1 stimulation is also used in treating diseases in which the body defensive mechanism is a Cell Mediated Immunity, including viral infections, as but not limited to influenza and common cold, Chronic and recurrent urinary tract infection, pelvic inflammatory diseases as neuroimmune appendicitis, cancer, crohns disease and facial palsy.

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REFERENCES

- 1- Help our children breath. Press release WHO v .av"/December 1998. World health organization press office, WHO web site: www.who.ch/
- 2- Barnes P J, The New England Journal of Medicine. Dec 23, 1999. Vol. 341, No. 26:
- 3- Villarubia, V.G.; Moreno, Koch M.C.; Calvo, C.; Gonzaiez, S.; Alvarez Mon, M. The immunosenescent phenotype in mice and humans can be defined by alterations in the natural immunity reversal by immunomodulation with oral AM3. The immunosenescent phenotype in mice and humans can be defined by alterations in the natural immunity reversal by immunomodulation with oral AM3. Immunopharmacol. Immunotoxicol, 1997;19(1): 53 74
 - 4- Moya P, Baixeras E, Barasoain I. Inmunoferon enhances the activities of early-type interferon inducers and natural killer cells. Immunopharmacol. Immunotoxicol. 1987, 9 (2-3); 234-56.
 - 5- Paulesu L, Bocci V, Pessina G P, et al. Interferon induction in rabbits after intraduodenal administration of a phosphorylated glycomannan-protein fraction of the cell wall of Candida albicans. Immunol. Lett. 1991, 27 (3); 231-5.
 - 6- Glocomannan containing antiobesity pharmaceuticals. Shimizu, Hideki (Shimizu Chemical K. K., Japan). Jpn. Kokai Tokkyo Koho JP 01224320 A2 7 Sep 1989 Heisei, 5 PP. (Japan) CODEN: JKXXAF. CLASS: ICM: A61K031-715. ICS: A23K001-16: A61K035-78.
- 20 APPLICATION: JP 88-48345 Mar 1988. DOCUMENT TYPE: Patent CA Section: 63 (Pharmaceuticals) Section cross-reference(s): 1.
 - 7- Medenica Rajko, D. Nigella sativa as a medicinal treatment. International Application No: PCT/US94/09660, International Filling Date: 25 Aug 1994, International Publication No: WO 95/05839, International Publication Date: 02 Mar 1995.
 - 8- SHAWKAT T. Extract solution and herbal mixture for treatment of hepatitis. US Patent No:5, 648, 089. Date of Patent Jul, 15, 1997.
 - 9- Sayed M D. Traditional medicine in health care. J Ethnopharmacol 1980 March; 2 (1): 19-22-
 - 10- Mahfouz M and El Dakhakhny M: chemical and pharmacological properties of the new anti
- 30 asthmatic drug, nigellone. Egypt Pharm Bul 1960: 42: 411 424.

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- 11- El Tahir KEH, Ashour MMS, a al; The respiratory effect of the volatile oil of the black seed (Nigella sativa) in guinea pig: elucidation of the michanism (s) of action. Gen Pharmacol 1993; 24: 1115 1122. (non relevant).
- 5 12- Aqcl MB: The calcium antagonistic effect of the volatile oil of Nigella sativa seeds. Jordar Ser B 1992; 119 133.
 - .13- Reicex M, Brandt W: Relaxant effects on tracheal and ileal smooth muscles of the guinea pig. Arzneim Forsch / Drug Res 1985; 35: 408 414.
 - 15- Boskababy & Shahabi. Bronchiodilatory and Anticholinergic effects of Nigella sative.... Iranian Journal of Medical Science (1997), 23(3-4), 127-133.
 - 16- Mutabagani & El-Mahdy. A study of the Anti-inflammatory activity of *Nigella sativa*... Saudi Pharmaceutical Journal (1997), 5(2) 110-113.
 - 17- Morton D L. Local therapy with biologic agents, Intralesional therapy: 691. Biologic therapy of cancer 1995 J.B.Lippincott Company, Philadelphia.
 - 18- Witt P L. Chemically defined immunomodulators and interferon inducers: 787. Biologic therapy of cancer 1995. J.B.Lippincott Company, Philadelphia.
 - 19- Akporiaye E T, Hersh E M. Cancer vaccines: clinical applications, Immune adjuvants: 635. Biologic therapy of cancer 1995. J.B.Lippincott Company, Philadelphia.
 - 20- ABPI, DATA SHEET, COMPENDIUM. 1995-1996: 555. Publisher: datapharm Publications Limited.
 - 21- Bjornsdottir, Cypcar DM. Asthma: An inflammatory mediator soup. Allergy 1999; 54: 55-61.
 - 22- Romagnani S. The Th1/Th2 paradigm and allergic disorders. Allergy 1998; 53 Suppl 46: 12 15. 7th International symosium on immunological, chemical and clinical problems of food allergy, Italy 4-7 October 1998.

- 23- Holgate ST, Corne J, Jardieu P,et al. Treatment of allergic airways disease with anti-IgE. Allergy 1998: 53 supplement 45 30 years with IgE: An international symposium on basic and clinical aspects of atopic allergy Stockholm, 1-2 September 1998: 83-88.
- 24- Palma Carlos A G, Palma Carlos M L, Santos M Conceicao, Melo Alcinda. Cytokines and asthma. J Invest Allergol Clin Immunol 1997September-October; 7(5) J of Invest Allergol Clin Immunol Vol 7 No 5 Interasma' 97 Annual Meeting Western Europe Chapter.Dec 3-51997.: 270-273.
 - 25- Menz G, Ying S, Durham SR. Molecular concepts of IgE-initiated inflammation in atopic and nonatopic asthma. Allergy 1998; 53 suppl 45 30 years with IgE: An international symposium on basic and clinical aspects of atopic allergy Stockholm, 1-2 September 1998: 15-
 - 26- Lebedin-YS; Raula-LA; Chuchalin-AG. Serum levels of inteleukin 4, inteleukin 6 and interferon-gamma following *in vivo* isotype-specific activation of IgE synthesis in humans. Int-Arch-Allergy-Appl-Immunol 1991; 95 (1) 92 4.
 - 27- Jankowska-R, Szalaty-H, Malolepszy-J, Sypula-A, Zielinska-Jenczylik-J. Production of interferon by leukocytes from patients with atopic and nonatiopic asthma. Arch-Immunol-Ther-Exp-Warsz. 1988; 36 (5): 523 6.
 - 28- WHO Position Paper Allergen immunotherapy: therapeutic vaccines for allergic diseases. Allergy 1998; 53 Supplement 44: 12-13.
- 29- Harbeck R J, Giclas P C. Lymphocyte stimulation with mitogen and antigens: 211-219.

 Diagnostic Immunology Laboratory Manual 1991. Raven press.
- 30- Jin Miaozhen; Yang, Fan. Pharmaceutical application of Konjac glucomannan. Guangdong Yiyao xueyuan xuebae, 10 (1), 1-3 (Chines) 1994.
 - CODEN:GYYXEI. ISSN:1005-2607. . DOCUMENT TYPE: Jornal General review CA section: 63 pharmaceuticals.
- 25 31- Ohya, Ynichi; Ihara, Kenji; Murata, Jun-ichi; Ouchi, Tatsuro. Biodegradation and immunological enhancement activity of dicarboxy-glucomannan having recognizable branched saccharide residues. Adv. Sci. Technol., 10 (Intelligent Materials and Systems), 273-280 (English) 1995. CODEN: ASETE5. DOCUMENT TYPE: Journal CA Section: 1(Pharmacology) Section cross-reference(s): 44.